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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,339	03/12/2002	Peter Jungblut	028622-0108	1997

7590 07/19/2004

Stephen A Bent
Foley & Lardner
Suite 500
3000 K Street NW
Washington, DC 20007-5109

EXAMINER	
SWARTZ, RODNEY P	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/890,339	Applicant(s) JUNGBLUT ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26April2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *27-45 and 48-62* is/are pending in the application.

4a) Of the above claim(s) *27-43,48-50 54-57 drawn to protein* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *44,45 and 48-62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *27-45 and 48-62* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/01*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

DETAILED ACTION

1. Applicants' Response to Restriction, received 26April2004, is acknowledged. Applicants elect, with traverse, Invention II, claims 44, 45, 48-50, and 51-57 drawn to DNA and methods of use.

Applicant's traversal is on the grounds that Inventions I and II are related and that search and examination of all of the inventions can be made without serious burden. This is not found persuasive because for the reasons put forth in the original restriction requirement. Invention I is drawn to protein as its special technical feature, while Invention II is drawn to DNA as its special technical feature. In addition, while the searches may overlap, the searches are not coextensive. The requirement is still deemed proper and is therefore made FINAL.

New claims 58-62 have been added. Claims 44, 48, 50, and 52 have been amended. Claims 46 and 47 have been cancelled.

2. Claims 27-45 and 48-62 are pending. Claims 27-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Also, claims 48-50 and 54-57 which read on protein composition and methods are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

3. Claims 44, 45, 48-50 and 51-62 drawn solely to DNA and methods of use are under consideration.

Priority Statement

4. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior

nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Specification

5. The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains embedded hyperlinks and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlinks and/or other form of browser-executable code. See MPEP § 608.01.

Page 42, line 5, "of" should be inserted between "strains pathogenic".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 48-50 and 54-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to compositions and methods of use of a nonelected invention, i.e., proteins.

9. Claim 51 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 51 depends from nonelected claim 27.

10. Claims 44, 45, and 48-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identification of proteins, does not reasonably provide enablement for identification and isolation of the claimed nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention – nucleic acid molecules coding for proteins which are differentially expressed in virulent *Mycobacterium* compared to avirulent strains of *Mycobacterium*, methods of making a vaccine using said nucleic acid molecules, methods of altering *Mycobacterium* induced disease using said vaccines, and methods of detecting *Mycobacterium* using said nucleic acid molecules.

The state of the prior art for general isolation of *Mycobacterium* nucleic acid molecules is well known. However, there is a lack of predictability in the art concerning the scope of the

instant claims, i.e., isolation and use of nucleic acid molecules coding for proteins which are differentially expressed in virulent *Mycobacterium* compared to avirulent strains of *Mycobacterium.*

The amount of direction/guidance/working examples present in the instant specification is insufficient to support the scope of the instant claims. The instant specification does teach the identification and isolation of proteins which are differentially expressed in *Mycobacterium tuberculosis* versus *Mycobacterium bovis* BCG. However, the specification does not teach the specific nucleic acids which actually encode these proteins. Instead, the specification merely cites references concerning the entire nucleic acid sequence of the microorganisms.

Thus, the quantity of experimentation necessary to fulfill the scope of the instant claims, i.e., identification, isolation, utilization in vaccine production, utilization in treatment regimens against *Mycobacterium* disease, and utilization in diagnostic methods using nucleic acid molecules entirely depends on first identifying proteins and then identification and isolation of the specific nucleic acid molecules involved.

Even with the relative skill of those in the art, the breadth of the claims constitute merely an invitation to experiment without a reasonable expectation of success for identifying and using unknown nucleic acid molecules for proteins which may be differentially expressed in virulent *Mycobacterium* compared to avirulent strains of *Mycobacterium.*

11. Claims 49, 51, 52, and 54 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identification of proteins, does not reasonably provide enablement for vaccines. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention – vaccine compositions comprising nucleic acids, methods of making vaccines, and methods of using vaccines to alter *Mycobacterium* diseases.

The state of the prior art concerning vaccine compositions is established for whole BCG in animals and humans, but subcomponent vaccines have, to date, been shown only to work in animal models, and there in limited success. Thus, there is a lack of predictability in the art for vaccines against *Mycobacterium* disease without some working examples.

The amount of direction/guidance/working examples present in the instant specification is insufficient to support the scope of the instant claims, i.e., vaccines. The specification merely compares protein presence/absence/variable expression between *M. tuberculosis* and *M. bovis* BCG. There are no working examples of vaccines in the specification using these limited proteins and no working examples of nucleic acid vaccines.

Therefore, due to the lack of working examples and insufficient guidance, the scope of the instant claims, i.e., vaccines, merely constitutes an invitation to experiment without a reasonable expectation of success.

12. Claims 44, 45, and 48-62 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for identification of proteins by comparison of *M. tuberculosis*

with *M. bovis* BCG, does not reasonably provide enablement for identification and isolation of nucleic acids. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention – nucleic acid molecules coding for proteins which are differentially expressed in any/all virulent *Mycobacterium* compared to any/all avirulent strains of *Mycobacterium*, methods of making a vaccine using said nucleic acid molecules, methods of altering *Mycobacterium* induced disease using said vaccines, and methods of detecting *Mycobacterium* using said nucleic acid molecules.

The state of the prior art for general isolation of *Mycobacterium* nucleic acid molecules is well known. However, there is a lack of predictability in the art concerning the scope of the instant claims, i.e., isolation and use of nucleic acid molecules coding for proteins which are differentially expressed in any/all virulent *Mycobacterium* compared to any/all avirulent strains of *Mycobacterium*.

The amount of direction/guidance/working examples present in the instant specification is insufficient to support the scope of the instant claims. The instant specification does teach

the identification and isolation of proteins which are differentially expressed in *Mycobacterium tuberculosis* versus *Mycobacterium bovis* BCG. However, the specification does not teach the specific nucleic acids which actually encode these proteins. Instead, the specification merely cites references concerning the entire nucleic acid sequence of the microorganisms.

Because of the lack of comparison of any/all virulent *Mycobacterium* with any/all other virulent *Mycobacterium*, how does one determine if a nucleic acid molecule encoding a protein expressed by, e.g., *M. tuberculosis*, but not expressed by, e.g., *M. phlei*, fulfills the scope of the claims.

Thus, the quantity of experimentation necessary to fulfill the scope of the instant claims, i.e., identification, isolation, utilization in vaccine production, utilization in treatment regimens against *Mycobacterium* disease, and utilization in diagnostic methods using nucleic acid molecules entirely depends on first identification of proteins and then identification and isolation of the specific nucleic acid molecules involved by comparison of any/all virulent *Mycobacterium* with any/all other avirulent *Mycobacterium*.

Even with the relative skill of those in the art, the breadth of the claims constitute merely an invitation to experiment without a reasonable expectation of success.

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

15. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER
Art Unit 1645

July 13, 2004